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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,379	07/01/2003	Oliver Hobert	5199-92	7972

7590 03/24/2005

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EXAMINER	
GAMETT, DANIEL C	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,379	HOBERT, OLIVER	
	Examiner	Art Unit	
	Daniel C. Gamett	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *11-39* is/are withdrawn from consideration.

5)☒ Claim(s) *1-3,5,7 and 9* is/are allowed.

6)☒ Claim(s) *4,6,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/12/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Claims 1-10 in the reply filed on 02/04/2005 is acknowledged. The traversal is on the ground(s) that Groups I-VII are clearly related to each other and are not independent. Applicant's arguments concerned three major areas: 1) the legal basis for the restriction requirement, 2) the explanations given in the Requirement for Restriction/Election as to the distinctness of the Groups, and 3) the role of classification in justifying the restriction requirement. These areas will be addressed in turn, as follows.

2. Regarding the legal basis for restriction, Applicants are indeed encouraged to claim all aspects their invention, but the phrase "all aspects their invention" is not equivalent to "multiple inventions". Applicant is referred to the following quotations from MPEP § 802.01, "The law has long been established that dependent inventions (frequently termed related inventions) such as used for illustration above may be properly divided if they are, in fact, "distinct" inventions, even though dependent," and MPEP § 803, "There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (see MPEP § 802.01, § 806.04," § 808.01) ***or*** distinct as claimed (see MPEP § 806.05 -§ 806.05(i))" (emphasis added). The cited sections of the MPEP set forth criteria for distinctness that are consistent with statute and legal precedent; these criteria are reiterated in each section of the requirement for restriction/election. For example, "Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01)." For each group, this

statement was followed by an explanation of how the groups being compared satisfy the criteria. Insofar as the criteria were indeed satisfied, as will be discussed below, restriction was proper.

3. Regarding, the explanations given in the Requirement for Restriction/Election as to the distinctness of the Groups, specific statements will be addressed in turn, beginning with the following quotes from the final paragraph of page 4:

a. "*Further, the Examiner has merely stated that Groups I, II, III and IV are unrelated with no explanation as to why the nucleic acids, vectors, and transformed cells of Group I are not used in the methods of Groups III or IV;*" Groups III and IV are methods, described in claims 20 and 23, respectively. While it might be possible to use a product of Group I in said methods, such use is not necessary in practice and is not required by the language of the method claims.

b. "*...how the antibody of Group II is chemically distinct from the nucleic acids, vectors, and transformed cells of Group I,*" The Examiner sees no need to elaborate on the statement that antibodies are not nucleic acids, vectors, or cells.

c. "*...how the methods of Groups III-VII do not use or rely on the antibody of Group III,*" While one might find a use for antibodies in carrying out the methods of Groups III-VII, such use is not necessary in practice and is not required by the language of the method claims.

d. "*...and how Groups III-VII have different modes of operation, different functions, different effects.*" The different modes of operation, different functions, and different effects were in fact explained in section 6 of the prior office action in which the different

measured endpoints, different method steps, different reagents, and different purposes are pointed out.

4. Regarding classification, Applicant contended that "... *the Examiner has not shown that a serious burden exists in examining the groups of claims, as five of the seven groups are in the same class, i.e. 435.*" This is not found persuasive because Class 435 comprises 70,435 issued patents in the USPTO full text database from 1976-present, as of March 8, 2005. Subclass 435/455, to which Groups VI and VII were classified, for example, has 1,989 patents. So, the placement of two inventions into the same class, or even the same subclass, does not indicate that the two inventions are so closely related that their searches will be coextensive. Furthermore, in no case was classification the sole reason for imposing the restriction requirement. Classification was cited as an indication that the inventions of the various groups each have a different status in the art. "Different status" entails different key concepts, terms, and methods that necessitate non-coextensive searches.

5. Finally, Applicant is reminded of the right to rejoinder of product and process claims set forth in section 9 of the requirement for restriction/election. Specifically, "Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04." Thus, it may be possible to rejoin the process claims if the elected claims are found allowable and the stipulations regarding dependency, scope, and amendments are adhered to; said stipulations are set forth in section 9 of the requirement for restriction/election and the sections of the MPEP cited therein.

6. The requirement is still deemed proper and is therefore made FINAL.

35 U.S.C. § 112, First Paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4, 6, 8, and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid having the sequence of SEQ ID NO: 1 and the rh133, n561 and n2400 mutant alleles thereof, recombinant vectors, cells, and methods of making the encoded protein, does not reasonably provide enablement for the mutant nucleic acids, proteins, vectors, cells, and methods of Claims 4, 6, 8, and 10. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. All claims are dependent from claim 4, which is drawn to an isolated nucleic acid that has a sequence identical to the sequence of SEQ ID NO.: 1, except for the presence of one or more missense mutations, nonsense mutations, point mutations, substitutions, deletions, insertions, polymorphisms, or rearrangements. This claim language permits a limitless number of variants. The specification, however, teaches only three mutants, designated rh133, n561 and n2400. These appear indistinguishable in the severity of the excretory phenotype, but surely not all missense mutations, nonsense mutations, point mutations, substitutions, deletions, insertions, polymorphisms, or rearrangements of the

sequence of SEQ ID NO:1 would be expected to have the same phenotype. The only disclosed assay for activity of the claimed nucleic acid is rescue of embryos with an exc-4 null mutant phenotype. Thus, isolation and characterization of each new variant would require extensive experimentation. Due to the large quantity of experimentation necessary to isolate and characterize mutants, the lack of direction/guidance presented in the specification regarding mutants other than rh133, n561 and n2400, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which established the unpredictability of the phenotype of variants, and the breadth of the claims which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Sulston, Accession No. AL132876.4, November 15, 1999. Sulston discloses a *C. elegans* YAC clone comprising 100% identity to SEQ ID NO:1 (see result 3 of the 10-612-379-1.rge sequence search, APPENDIX). The sequence disclosed by Sulston thus is "an isolated nucleic acid that has a sequence identical to the sequence of SEQ ID NO.: 1, except for the presence of one or more ...deletions" as recited in claim 4, in a recombinant vector, as in claim 6. As AL132876.4

was known more than 1 year before the earliest effective filing date of the instant specification, rejection under 35 U.S.C. 102(b) is proper.

Conclusion

11. Claims 4, 6, 8, and 10 are rejected. Claims 1-3, 5, 7, and 9 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

DCG
Art Unit 1647
15 March 2005

ELIZABETH KEMMERER
PRIMARY EXAMINER

APPENDIX

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RESULT 3
CEY105E8A/c
LOCUS       CEY105E8A              277607 bp    DNA     linear   INV 12-OCT-2004
DEFINITION  Caenorhabditis elegans YAC Y105E8A, complete sequence.
ACCESSION   AL132876
VERSION     AL132876.4  GI:18376550
KEYWORDS    HTG.
SOURCE      Caenorhabditis elegans
  ORGANISM  Caenorhabditis elegans
            Eukaryota; Metazoa; Nematoda; Chromadorea; Rhabditida;
            Rhabditoidea; Rhabditidae; Peloderinae; Caenorhabditis.
REFERENCE   1
  AUTHORS   none.
  TITLE     Genome sequence of the nematode C. elegans: a platform for
            investigating biology. The C. elegans Sequencing Consortium
  JOURNAL   Science 282 (5396), 2012-2018 (1998)
  MEDLINE   99069613
   PUBMED   9851916
  REMARK    The C.elegans Sequencing Consortium.
REFERENCE   2  (bases 1 to 277607)
  AUTHORS   Sulston,J.E.
  TITLE     Direct Submission
  JOURNAL   Submitted (11-OCT-2004) Nematode Sequencing Project, Sanger
            Institute, Hinxton, Cambridge CB10 1SA, England and Department of
            Genetics, Washington University, St. Louis, MO 63110, USA. E-mail:
            jes@sanger.ac.uk or rw@nematode.wustl.edu E-mail: worm@sanger.ac.uk
COMMENT     On Jan 25, 2002 this sequence version replaced gi:15130764.
            Coding sequences below are predicted from computer analysis, using
            predictions from Genefinder (P. Green, U. Washington), and other
            available information.
            Current sequence finishing criteria for the C. elegans genome
            sequencing consortium are that all bases are either sequenced
            unambiguously on both strands, or on a single strand with both a
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dye primer and dye terminator reaction, from distinct subclones. Exceptions are indicated by an explicit note.
IMPORTANT: This sequence is NOT necessarily the entire insert of the specified clone. It may be shorter because we only sequence overlapping sections once, or longer because we arrange for a small overlap between neighbouring submissions.
For a graphical representation of this sequence and its analysis see:- http://wormbase.sanger.ac.uk/perl/ace/elegans/seq/sequence?name=Y105E8A
For a graphical representation of this sequence and its analysis see:- http:
IMPORTANT: This sequence is not the entire insert of clone Y105E8A. It may be shorter because we only sequence overlapping sections once, or longer because we arrange for a small overlap between neighbouring submissions.
The true left end of clone Y54E5 is at 356131 in this sequence. The true right end of clone P49B2 is at 104 in this sequence. The start of this sequence (1. .104) overlaps with the end of sequence Z81543. The end of this sequence (277504. .277607) overlaps with the start of sequence AL132877.

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Thu Mar 10 08:34:28 2005 **us-10-612-**

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Qy        241 ATGATTGAAGAGGAAAAAGAGCTGACATACACTGATAATCGAGAGATTGAAGGACGGATC 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     185315 ATGATTGAAGAGGAAAAAGAGCTGACATACACTGATAATCGAGAGATTGAAGGACGGATC 185256

Qy        301 TTTCATTTGGCAAAGGAATTCAATGTTCCACTCTTTGAAAAGGATCCATCCGCTGAGAAG 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     185255 TTTCATTTGGCAAAGGAATTCAATGTTCCACTCTTTGAAAAGGATCCATCCGCTGAGAAG 185196

Qy        361 AGAATAGAGAACTTGTACAGG 381
              |||||||||||||||||||||
Db     185195 AGAATAGAGAACTTGTACAGG 185175


RESULT 4
CBRG35I24
LOCUS       CBRG35I24              24174 bp    DNA     linear   INV 04-NOV-2000
DEFINITION  Caenorhabditis briggsae cosmid G35I24, complete sequence.
ACCESSION   AC084558
VERSION     AC084558.1  GI:11095008
KEYWORDS    HTG.
SOURCE      Caenorhabditis briggsae
  ORGANISM  Caenorhabditis briggsae
            Eukaryota; Metazoa; Nematoda; Chromadorea; Rhabditida;
            Rhabditoidea; Rhabditidae; Peloderinae; Caenorhabditis.
REFERENCE   1  (bases 1 to 24174)
  AUTHORS   Washington University Genome Sequencing Center.
  TITLE     The C. briggsae Genome Sequencing Project
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 24174)
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